

July 25, 1995

David Werdegar, M.D., MPH Director, Health Policy and Planning Division State Wide Health Planning and Development 1600 Ninth Street, #400 Sacramento, CA 95814

RE: California Hospitals and Outcomes Project: Acute Myocardial Infarction

Dear Dr. Werdegar:

We have had an opportunity to review the preliminary confidential draft of the 1994 California Hospitals Outcome Project as well as the specific Good Samaritan Hospital patient data. Once again, we have paid particular attention to the acute myocardial infarction data. As was true at the time of the last study in 1993, we continue to endorse strongly all efforts to measure clinical outcomes and continue to devote considerable resources as an institution to do so. We find the methodology in this study very impressive and the amount of work devoted to it admirable. Careful review of the study and our particular patient experience, however, highlight problems with the data which will need to be addressed before meaningful comparisons between institutions can be made.

Good Samaritan Hospital has become regarded as a leader in cardiovascular care in Southern California and is widely recognized as a tertiary Center of Excellence for referral of patients for interventional cardiology, electrophysiology and cardiothoracic surgery. The hospital has a national and international reputation for leadership in this area and thus it causes us considerable concern when one of the two models used in this study identifies the facility as achieving significantly worse than expected outcomes for management of acute myocardial infarction. We became concerned that perhaps

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we had concentrated too intently on regional referral practices and neglected the management of patients presenting directly to the institution for initial care of acute MI. We carefully reviewed the cases included in this study:

- 1. We were able to review 30/37 mortalities.
- 2. By patient or family request, owing to multiple other medical problems and co-morbidities, 9 patients were declared "Do Not Resuscitate" and were not treated aggressively.
- 3. Of the remaining 21 patients, 13 presented with cardiogenic shock and had a relentlessly deteriorating clinical course from which survival would have been distinctly unusual. Of the remaining 8 patients, 5 had prehospital arrest, 3 of whom had severe anoxic brain damage and the remaining 2 had multiple cardiac arrests in the hospital prior to death. Two other remaining patients may have been incorrectly assigned the diagnosis of acute myocardial infarction.

Importantly, in no case could we find significant quality of care or management issues which might have contributed to a poor outcome for an otherwise survivable acute myocardial infarction.

Based on this experience, we feel very strongly that statistical techniques such as model A, which do not include important clinical variables in risk adjustment are fraught with potential for error. We understand your concern that the data do not adequately discriminate between presenting medical conditions and potential complications. In this case, however, cardiogenic shock is rarely a complication of treatment and much more commonly represents the most severe form of infarction and offers an extremely grave prognosis when present on admission or shortly after admission (as was true in a large number of the patients in our population). Cardiogenic shock is a powerful predictor of adverse outcome. Certainly one can argue that cardiogenic shock may represent a data complication of delayed or inadequate treatment. However, that is clearly not the case in our population, and I'm doubtful that it would pose a common occurrence in the population at large. This observation is supported by the fact that, not surprisingly, when cardiogenic shock and pulmonary edema are included in the model (model B), the hospital is considered "not significantly different than expected." Thus it seems clear to us that model A is significantly limited by unmeasured severity of illness. At least in our case, model A very poorly reflects quality of care.

Based upon this review, our distinct impression is that, given the very high risk nature of the patient population presenting to our hospital emergency room for acute MI, the quality of care is significantly better than one could expect. This then draws additional attention to our underlying concern about the utility of using an administrative data set for clinical outcomes assessment. Even though model B incorporates more "clinical" variables into the analysis, and is clearly an improvement over Model A, we would remain very skeptical of data which provide no information about the patient's physiologic or functional status such as blood pressure, heart rate and laboratory values. We understand the limitations and costs of creating new data systems to collect such specific clinical information. However, by your own admission, administrative data only correlate "fairly well with more detailed clinical data." When multiple interested parties are looking to compare providers regarding their treatment outcomes, risk adjustment comparisons using data which only "correlate fairly well" are fraught with problems and clearly unfair.

Finally, we have technical concerns which arose after our review of volume II, the technical appendix:

- 1. Page 9-1. The use of bi-variate analysis to identify and eliminate low frequency risk factors and to eliminate risk factors from the model is a common, but statistically questionable practice. Please see enclosed draft manuscript.
- 2. Page 11-6. <u>Both models A and B did not pass the "goodness of fit" test.</u> See table 11.1 page 11-10. This suggests that neither model was "good enough" to predict mortality.
- 3. Page 12-2. The formulas used to calculate the 95% confidence intervals may be incorrect. See Bickel and Doksum. <u>Mathematical Statistics</u>, page 160.

In summary, we strongly endorse efforts to measure clinical outcomes and believe that Good Samaritan Hospital will fare very well in any interinstitutional comparisons when adequately adjusted for severity of illness. However, any risk adjustment tool which does not directly accurately and completely address clinical characteristics of the patient population should be used with great caution. Our report is supported by our experience in the 1994 outcomes project. By your own admission, "this summary demonstrates that [these] risk models compare favorably with others based on administrative data, but are probably inferior to those based on more detailed clinical data." We strongly encourage development of systems to acquire these more detailed clinical data.

Sincerely yours,

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